

Food and Drug Administration, HHS

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nodular worm (*Oesophagostomum*) infections.

(ii) It is added to feed at 0.4 gram pyrantel tartrate per pound of nonpelleted ration. The ration is administered as a single treatment as the sole ration at the rate of 1 pound per 40 pounds of animal weight for animals up to 200 pounds. Animals 200 pounds and over are administered 5 pounds of ration per animal.

(iii) Fast pigs over night for optimum results. Water should be made available to animals during fasting and treatment periods. Consult veterinarian before using in severely debilitated animals. The drug should be used immediately after the package is opened.

(iv) Warning: Do not treat within 24 hours of slaughter.

(3) Horses and colts:

(i) For the removal and control of infections from the following mature parasites: Large strongyles (*Strongylus vulgaris*, *Strongylus edentatus*, *Strongylus equinus*), small strongyles (*Trichonema* spp., *Triodontophorus*), pinworms (*Oxyuris*), and large roundworms (*Parascaris*).

(ii) It is administered as a single dose at 12.5 milligrams of pyrantel tartrate per 2.2 pounds of body weight mixed with the usual grain ration.

(iii) It is recommended that severely debilitated animals not be treated with this drug.

(iv) Warning: Do not use in horses or colts intended for food.

[40 FR 13838, Mar. 27, 1975, as amended at 59 FR 28769, June 3, 1994; 69 FR 41427, July 9, 2004; 76 FR 40229, July 8, 2011]

§ 520.2075 Robenacoxib.

(a) *Specifications*. Each tablet contains 6 milligrams (mg) robenacoxib.

(b) *Sponsors*. See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use in cats*—(1) *Amount*. Administer 0.45 mg per pound (lb) (1 mg/kilogram (kg)) once daily.

(2) *Indications for use*. For the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy, and castration in cats weighing at least 5.5 lb (2.5 kg) and at least 4 months of age; for up to a maximum of 3 days.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[76 FR 18648, Apr. 5, 2011, as amended at 79 FR 10964, Feb. 27, 2014]

§ 520.2098 Selegiline hydrochloride tablets.

(a) *Specifications*. Each tablet contains either 2, 5, 10, 15, or 30 milligrams of selegiline hydrochloride.

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use—Dogs*—(1) *Dosage*. 1 milligram per kilogram (0.45 milligram per pound) of body weight.

(i) *Indications for use*. For control of clinical signs associated with uncomplicated pituitary-dependent hyperadrenocorticism in dogs.

(ii) *Limitations*. Administer orally once daily. If no improvement in clinical signs or physical examination findings after 2 months of therapy, increase dose to a maximum of 2 milligrams per kilogram once daily. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Dosage*. 0.5 to 1.0 milligram per kilogram of body weight once daily.

(i) *Indications for use*. For the control of clinical signs associated with canine cognitive dysfunction syndrome.

(ii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[62 FR 34632, June 27, 1997; 62 FR 55159, Oct. 23, 1997, as amended at 63 FR 29551, June 1, 1998; 64 FR 2122, Jan. 13, 1999]

§ 520.2100 Selenium, vitamin E capsules.

(a) *Specifications*. The capsules contain 2.19 milligrams of sodium selenite (equivalent to 1 milligram of selenium) and 56.2 milligrams of vitamin E (68 I.U.) (as d-alpha tocopheryl acid succinate) or 0.548 milligram of sodium selenite (equivalent to .25 milligram of selenium and 14 milligrams of vitamin E (17 I.U.) (as d-alpha tocopheryl acid succinate).)

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) The drug is intended for use as an aid in alleviating and controlling inflammation, pain,

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and lameness associated with certain arthropathies in dogs.

(2) The capsules are administered orally with the larger capsules administered at a dosage level of 1 capsule per 20 pounds of body weight to a maximum of 5 capsules with the dosage repeated at 3 day intervals until a satisfactory therapeutic response is observed. A maintenance dosage is then administered consisting of 1 capsule per 40 pounds of body weight, with a minimum of 1 capsule per 40 pounds of body weight, with a minimum of 1 capsule, given every 3 days, or 7 days, or longer, as required to maintain improvement or an asymptomatic condition. For dogs under 20 pounds of body weight, the small capsules are administered orally at a dosage level of 1 per 5 pounds of body weight with a minimum of 1 capsule which dosage is repeated at 3 day intervals until a satisfactory response is observed then a maintenance regimen is initiated with 1 capsule per 10 pounds of body weight, minimum of 1 capsule, every 3 days, or 7 days, or longer as required to maintain continued improvement or an asymptomatic condition.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 52 FR 7832, Mar. 13, 1987; 52 FR 9756, Mar. 26, 1987]

§ 520.2123 Spectinomycin oral dosage forms.

§ 520.2123a Spectinomycin tablets.

(a) *Specifications.* Each tablet contains spectinomycin dihydrochloride pentahydrate equivalent to 100 milligrams (mg) spectinomycin.

(b) *Sponsor.* See No. 061623 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* Administer orally to provide 10 mg per pound (lb) of body weight twice daily. Dosage may be continued for 4 consecutive days.

(2) *Indications for use.* For the treatment of infectious diarrhea and gastroenteritis caused by organisms susceptible to spectinomycin.

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(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[73 FR 6607, Feb. 5, 2008]

§ 520.2123b Spectinomycin powder.

(a) *Specifications.* Each gram (g) of powder contains spectinomycin dihydrochloride pentahydrate equivalent to 0.5 g spectinomycin.

(b) *Sponsor.* See No. 061623 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.600 of this chapter.

(d) *Conditions of use in chickens.* It is administered in the drinking water of growing chickens as follows:

(1) *Indications for use and amounts—(i)* For increased rate of weight gain and improved feed efficiency in broiler chickens, administer 0.5 g per gallon of water as the only source of drinking water for the first 3 days of life and for 1 day following each vaccination.

(ii) As an aid in controlling infectious synovitis due to *Mycoplasma synoviae* in broiler chickens, administer 1 g per gallon of water as the only source of drinking water for the first 3 to 5 days of life.

(iii) As an aid in the prevention or control of losses due to CRD associated with *M. gallisepticum* (PPLO) in growing chickens, administer 2 g per gallon of water as the only source of drinking water for the first 3 days of life and for 1 day following each vaccination.

(2) *Limitations.* Do not administer to laying chickens. Do not administer within 5 days of slaughter.

[73 FR 6607, Feb. 5, 2008]

§ 520.2123c Spectinomycin solution.

(a) *Specifications.* Each milliliter of solution contains spectinomycin dihydrochloride pentahydrate equivalent to 50 milligrams (mg) spectinomycin.

(b) *Sponsors.* See Nos. 000856, 000859, and 061623 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.600 of this chapter.

(d) *Conditions of use in swine—(1) Amount.* Administer 5 mg per pound (lb) of body weight orally twice daily for 3 to 5 days.

(2) *Indications for use.* For the treatment and control of porcine enteric